

Remarks

Claims 1-30 were previously pending in the subject application. By this amendment claims 2, 3, 6, 8, 12-27, 29 and 30 have been canceled and claims 1, 4 and 5 have been amended. Support for these amendments can be found throughout the subject specification including, for example, at page 7, lines 10-12; page 12, lines 12-13; and page 15, lines 4-6. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, the applicants acknowledge that the subject matter of claims 12-27 is withdrawn as being directed to non-elected inventions. By this Amendment, the non-elected subject matter has been canceled without prejudice.

The undersigned wishes to thank Examiner Patten for the courtesy of the personal Examiner Interview conducted with the undersigned on February 22, 2002. During that Examiner Interview it was stressed that the applicants have provided sufficient teachings to enable others skilled in the art to identify and use other microbes in the claimed *in vitro* process for growing *Pasteuria*. It was also noted that the applicants could clarify the scope of the claimed subject matter by amending the claims to provide more specific details of the microbes which can be used according to the subject invention. The applicants have endeavored to amend their claims herein consistent with the substance of the Examiner Interview. Favorable consideration of these amended claims is respectfully requested.

The specification has been objected to under 35 U.S.C. §112, first paragraph. By this amendment, the subject specification and claims have been amended to include the ATCC identification number and date of deposit. The culture deposit was made pursuant to the terms of the Budapest Treaty. A copy of the ATCC Deposit Receipt is attached herewith.

Claims 2-11 and 29-30 have been rejected under 35 U.S.C. §112, first paragraph. The applicants believe that the claims, as filed, were fully enabled; however, the claims have been

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amended herein to lend greater clarity to the claimed subject matter. The applicants respectfully request reconsideration of this rejection to the extent that it might be applied to the claims now presented for examination.

The applicants have unexpectedly discovered a process which, for the first time, makes it possible to efficiently grow *Pasteuria* endospores *in vitro*. This is a very important contribution to the art because *Pasteuria* are known to be effective biological control agents for nematodes. Crop losses due to phytopathogenic nematodes are in the billions of dollars each year. Efforts to control nematodes with chemicals take a heavy toll on the environment. Alternatives to chemical control strategies have been desperately needed for years.

Although *Pasteuria* was first reported as far back as 1888, all attempts to culture the microbe *in vitro* have failed to produce a viable means of producing endospores. Without the ability to grow *Pasteuria in vitro* it is not possible to produce enough *Pasteuria* to effectively address the massive nematode problem. Therefore, there remains in this art a great need for a method of producing *Pasteuria* by spore formation following true *in vitro* growth of the vegetative phase of *Pasteuria* on an artificial growth medium consisting of inexpensive, readily available materials. Such systems were not known until the subject invention.

The applicants' ability to produce *Pasteuria in vitro* has enormous implications for the development of this technology for the replacement of toxic nematocides such as methyl bromide. Like many pioneering inventions the applicants' discovery of their simple, but unique, process was largely the result of serendipity. Standard methodology in this field calls for the sterilization of culture media. The current applicants discovered, quite by chance, that sterilization of the media kills the very microbes which make *in vitro* culture techniques possible for *Pasteuria*.

The applicants initially isolated and identified one particular microbe which could be used to support *Pasteuria* growth. In the subject application the applicants also have provided a specific nucleotide sequence which can be used to identify other such microbes. Armed with this information, as well as the other detailed information provided in the subject application, the skilled artisan could readily, without undue experimentation, identify other microbes which could be used to

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promote *in vitro* *Pasteuria* growth.

It should be noted that the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . A considerable amount of experimentation is permissible, if it is merely routine . . ." (emphasis added). *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988). In the current case, any experimentation needed to identify other microbes would be routine given the guidance provided in the subject application. This guidance includes the identification of the microbes as being associated with nematodes as well as providing a specific DNA sequence.

The applicants respectfully submit that, to limit their patent coverage to the one specific deposited strain of bacteria, would essentially eviscerate their patent protection. Others skilled in the art, with minimal effort, could readily identify other microbes associated with nematodes which could be used to support *in vitro* growth of *Pasteuria*.

The Federal Circuit's predecessor, the Court of Customs and Patent Appeals (CCPA), has directly addressed the issue of claim scope for pioneer inventions. In addressing the enablement of relatively broad claims based on a limited disclosure the CCPA noted:

On remand, appellants may be found to have been in fact the first to conceive and reduce to practice "a solid polymer" as set forth in claim 13. As pioneers, if such they be, they would deserve broad claims to the broad concept. What were once referred to as "basic inventions" have led to "basic patents," which amounted to real incentives, not only to invention and its disclosure, but to its prompt, early disclosure. . . Appellants disclosed, as the only then existing way to make such a polymer, a method of making the crystalline form. . . To restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restriction is merely to state a policy against broad protection for pioneer inventions, a policy both shortsighted and unsound from the standpoint of promoting progress in the useful arts, the constitutional purpose of the patent laws. See *In re Goffe*, 542 F.2d 564, 191 USPQ 429 (CCPA 1976). (emphasis added).

It is well settled in the Patent Law that pioneer inventions are entitled to a scope of protection which is commensurate with the contribution made to the art. Here, the current applicants have

made an enormous contribution by making it possible, for the first time, to efficiently and easily grow a biocontrol agent which is urgently needed to help replace toxic chemicals that pollute our environment.

The claims as now presented clearly delineate the scope of the claimed subject matter as that which is taught in detail in the applicants' specification. Specifically, the characteristics of particular microbes which facilitate *in vitro Pasteuria* growth are recited. The subject application gives ample disclosure regarding the use of these microbes in the applicants' *in vitro* system. Thus, a person skilled in the art could readily make and use the invention, as claimed, without undue experimentation. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 29 and 30 have been rejected under 35 U.S.C. §112, first paragraph. By this amendment, claims 29 and 30 have been canceled, thus rendering this rejection moot.

Claims 1, 9, 10 and 28 have been rejected under 35 U.S.C. §102(b) as being anticipated by Reise (1998) or Reise (1991). Also, claims 1, 9-11 and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Reise (1998) or Reise (1991). As noted above, the applicants have set forth herein amendments to the claims which more clearly delineate the claimed subject matter. The outstanding prior art rejections have thus been rendered moot.

For the record, the applicants respectfully submit that the claims as originally filed were not anticipated by, or obvious in view of, the cited references. It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSI/H Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference.

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SSIH, supra; Kalman [v. Kimberly-Clarke, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The cited references do not disclose or suggest the applicants' unique method which makes it possible to have a sustained *in vitro* culture of *Pasteuria*. Furthermore, as noted above, the applicants' inventive process could not have been arrived at if conventional sterilization techniques had been used. Thus, there was no motivation or suggestion in the art to arrive at the current invention. Without such a suggestion or motivation, a finding of obviousness is improper.

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicants' invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art" *In re Dow Chemical Co., supra* at 1531. In the references cited, one finds neither.

Accordingly, the applicants respectfully submit that their unique and advantageous *in vitro* method for growing *Pasteuria* is patentable over the prior art.

In view of the foregoing remarks and the amendments above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

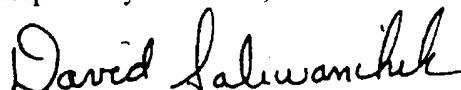
The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Petition and Fee for Extension of Time
Copy of ATCC Deposit Receipt

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Marked up Version of Amended Specification

Please substitute the following paragraph at page 4, lines 17-24 to read as follows:

A further aspect of the subject invention concerns the identification of helper factor(s) which, when present in *Pasteuria* growth medium, facilitate the *in vitro* growth of the *Pasteuria*. In one embodiment, the helper factor is a microorganism. A specific isolate of this helper factor has been deposited with the American Type Culture Collection and has been assigned the deposit number ATCC PTA-2324. In a further embodiment, the helper factor is a chemical compound which, when present in the *Pasteuria* growth medium, facilitates the *in vitro* growth of *Pasteuria*. Specifically exemplified herein is the helper factor designated HF-1 which can be obtained from the culture designated ATCC PTA-2324.

Please substitute the following paragraph at page 8, lines 8-12 to read as follows:

A further aspect of the subject invention pertains to the motile rod organisms which are associated with the ability of the *Pasteuria* to grow *in vitro*. A culture of the microbes has been deposited with the American Type Culture Collection (ATCC), [12301 Parklawn Drive, Rockville, Maryland 20852 USA] 10801 University Blvd., Manassas, VA 20110-2209. The deposit has been assigned accession number ATCC No. PTA-2324 by the repository and was deposited on August 2, 2000.

Marked-up Version of Amended Claims:Claim 1 (amended):

A method for producing *Pasteuria* endospores *in vitro*, said method comprising introducing *Pasteuria* into a growth medium, wherein said growth medium comprises a microorganism or a chemical compound produced by a microorganism, wherein said microorganism is found in association with nematodes and has DNA which hybridizes with SEQ ID NO. 1 under moderate to high stringency conditions; wherein said method comprises growing the *Pasteuria* in said growth medium, and obtaining said endospores.

Claim 4 (amended):

The method, according to claim [3] 1, wherein said microorganism is selected from the group consisting of *Enterobacter cloacae* and *Pantoea* spp.

Claim 5 (amended):

The method, according to claim 3, wherein said microorganism has all the identifying characteristics of ATCC [] PTA-2324.

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